



**[Billing Code 4140-01-P]**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Availability of the Report on the International Workshop on Alternative Methods To Reduce, Refine, and Replace the Use of Animals in Vaccine Potency and Safety Testing: State of the Science and Future Directions**

**AGENCY:** Division of the National Toxicology Program (DNTP), National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH)

**ACTION:** Availability of Workshop Report

**SUMMARY:** The NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) announces availability of the report on the “International Workshop on Alternative Methods To Reduce, Refine, and Replace the Use of Animals in Vaccine Potency and Safety Testing: State of the Science and Future Directions.” The report was published as an issue of the journal *Procedia in Vaccinology*, and is available on the journal’s website at <http://www.sciencedirect.com/science/journal/1877282X>. A limited number of CDs and printed copies of the report are available from NICEATM (see ADDRESSES).

**ADDRESSES:** Requests for copies of the report should be sent by mail, fax, or email to Dr. William S. Stokes, NICEATM Director, NIEHS, P.O. Box 12233, MD K2-16, Research Triangle Park, NC, 27709, (phone) 919-541-2384, (fax) 919-541-0947, (email) [niceatm@niehs.nih.gov](mailto:niceatm@niehs.nih.gov).

**FOR FURTHER INFORMATION CONTACT:** Dr. William S. Stokes: (telephone) 919-541-2384, (fax) 919-541-0947, or (email) [niceatm@niehs.nih.gov](mailto:niceatm@niehs.nih.gov).

## **SUPPLEMENTARY INFORMATION:**

### **Background**

Regulatory authorities require post-licensing potency and safety testing of human and veterinary vaccines to ensure their effectiveness and minimize potential adverse health effects. However, such testing requires large numbers of animals and accounts for the majority of animals reported to the USDA with unrelieved pain and distress. Accordingly, identification and promotion of alternative methods that can reduce, refine, or replace the use of animals for vaccine potency and safety testing is one of the four highest priorities of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), an interagency committee of the Federal government administered by NICEATM.

To address this priority, NICEATM and ICCVAM, along with international partners organized an “International Workshop on Alternative Methods To Reduce, Refine, and Replace the Use of Animals in Vaccine Potency and Safety Testing: State of the Science and Future Directions,” which took place on September 14 - 16, 2010 at NIH in Bethesda, Maryland. The report of the workshop is now available.

### **Workshop Goals and Outcomes**

The goals of the workshop were to (1) review the state of the science of alternative methods currently available and/or accepted for use that can reduce, refine (enhance animal well-being and lessen or avoid pain and distress), and replace animal use in vaccine potency and safety testing, and discuss ways to promote their implementation; (2) identify knowledge and data gaps that should be addressed to develop alternative methods that can further reduce, refine, and/or replace the use of animals in vaccine potency and safety testing; and (3) identify and prioritize research, development, and validation efforts needed to address these knowledge and

data gaps in order to advance alternative methods for vaccine potency and safety testing while ensuring the protection of human and animal health.

The workshop report is comprised of 27 papers that summarize the plenary session presentations and the conclusions and recommendations developed by the workshop participants during six breakout group sessions. The report recommends vaccines that should have the highest priority for future reduction, refinement, and replacement efforts. Other key recommendations include:

- Procedures such as earlier humane endpoints should be developed and implemented immediately to reduce or avoid the pain and distress experienced by animals for vaccines that still require live-agent challenge testing. Until non-animal tests are available, development of serological assays should also be considered as a way to avoid challenge testing.
- Specific non-animal approaches that have successfully replaced animals for some vaccine potency testing should be developed for vaccines currently requiring animals through identification, purification, and characterization of vaccine protective antigens.
- International harmonization and cooperation efforts and closer collaborations between human and veterinary vaccine researchers should be enhanced in order to support more rapid progress towards reduction, refinement, and replacement of animal use for vaccine testing.

The workshop was organized by NICEATM and ICCVAM in partnership with the European Centre for the Validation of Alternative Methods, the Japanese Center for the Validation of

Alternative Methods, and Health Canada. The workshop was co-sponsored by the Society of Toxicology.

### **Background Information on NICEATM and ICCVAM**

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. The ICCVAM Authorization Act of 2000 (42 U.S.C. 285I-3) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. ICCVAM conducts technical evaluations of new, revised, and alternative testing methods with regulatory applicability and promotes the scientific validation and regulatory acceptance of toxicological and safety testing methods that more accurately assess the safety and hazards of chemicals and products and that reduce, refine, or replace animal use.

NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM technical evaluations and related activities, and conducts independent validation studies to assess the usefulness and limitations of new, revised, and alternative test methods and strategies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods and strategies applicable to the needs of Federal agencies. Additional information about NICEATM and ICCVAM can be found on the NICEATM–ICCVAM website (<http://iccvam.niehs.nih.gov>).

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